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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,920	05/11/2007	Shigeru Nakajima	125192.00401	7896

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PEPPER HAMILTON LLP
ONE MELLON CENTER, 50TH FLOOR
500 GRANT STREET
PITTSBURGH, PA 15219

EXAMINER	
MUKHOPADHYAY, BHASKAR	
ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,920	NAKAJIMA ET AL.	
	Examiner	Art Unit	
	BHASKAR MUKHOPADHYAY	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *preliminary amement of Aug 08, 2006.*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20061221*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it exceeds more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objection

2. Claim1 is objected to because of the following informalities: Claim 1 recites “animal (including human)". In order to avoid confusion about whether the claim actually requires maintaining the body protein and reducing only the body fat of animals or humans, applicants are advised to remove the parentheses from this phrase.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites “high histidine content" but does not disclose what is meant by "high". The term high in claim 1 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a

standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

5. Claim 2 recites the limitation 'said active ingredients' in line 2. There is insufficient antecedent basis for this limitation in the claim. It is to be noted that independent claim 1 on which claim 2 depends has been amended to delete 'active ingredients'.

6. Claim 3 recites "12,000 mg - 20,000 mg weight percent" . It is not clear how the amount of histidine is measured in both mg and percent at the same time.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, and 5, are rejected under 35 U.S.C. 102 (b) as being anticipated by Nakajima S et al., (NPL: Nakajima S et al., J Jpn. Soc. Nutr. Food Sci. 53: 207-214, 2000).

8. Regarding claim 1, Nakajima S et al. teach about a material for processed food for weight reduction diets (Abstract, e.g. 'obesity'), comprising protein with a high histidine content (Abstract, e.g. 'histidine is enriched in tuna and bonita'), extracted from fish (Abstract, e.g. 'histidine enriched protein'), to maintain body protein and reduce only the body fat of humans (Abstract, e.g. 'intake of histidine in 64 male and female students). Given that Nakajima discloses protein with histidine content as presently claimed which is used in weight reduction diet as presently claimed, it is clear that the protein with high histidine content would inherently maintain body protein and reduce only body fat.

9. Regarding claim 2, although Nakajima S et al. do not disclose 'histidine are extracted from Bonito essence by membrane concentration", it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985). Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed

product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

Therefore, absent evidence of criticality regarding the presently claimed process and given that Nakajimo S et al. meet the requirements of the claimed material, Nakajima et al. clearly meet the requirements of present claim 2.

10. Regarding claim 5, Nakajima S et al. teach about a dietary processed food, processed using the material for processed food for weight reduction diet (Abstract, e.g. 'obesity, and 'orally administered histidine- enriched protein on food intake' and in page 213, Table 3, e.g. one example, Food as 'Yellow tuna' 87 mg His / g protein).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action.

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

a. Determining the scope and contents of the prior art.
b. Ascertaining the differences between the prior art and the claims at issue.
c. Resolving the level of ordinary skill in the pertinent art.
d. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 2-4, are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima S et al., (NPL: Nakajima S et al., J Jpn. Soc. Nutr. Food Sci. 53: 207-214, 2000) in view of Ogura T et al., (S63-101370).

Regarding claim 2, Nakajima S et al teach about histidine enriched protein and source is from Bonito (Abstract, e.g. 'histidine is enriched in tuna and bonito').

Nakajima S et al. do not teach about histidine extraction from Bonito essence by membrane concentration.

Ogura T et al. teach about histidine extraction from Bonito essence by membrane concentration (under the heading, 'Means of solving the problems', in 2nd paragraph, 'a suitable semi-permeable membrane used here' and in 4th paragraph, e.g. 'As described above, with regard to the two tasks mentioned above by means of 1) removing a high-molecular substance with a semi-permeable membrane and 2) …….crystallization of His).

It would have been obvious to one of ordinary skill in the art at the time of invention to include the teaching of Ogura T et al. into Nakajima et al. One of ordinary

skill in the art would have been motivated to purify histidine from high-molecular weight substances using the 'membrane concentration' step with a semi-permeable membrane followed by crystallization of Histidine from the solution given that membrane concentration method is inexpensive and results in high purity product (Purpose of invention and Example 1).

14. Regarding claim 3, Nakajima S et al teach about histidine enriched protein and source is from Bonito (Abstract, e.g. 'histidine is enriched in tuna and bonito').

Nakajima S et al do not teach about mg wt percent of histidine is contained in Bonito.

Ogura T et al. teach about histidine in the amount of 8-12% (under the heading, 'problems to be solved by this invention', 1st paragraph, a) bonito broth contains natural His in the amount of 8-12% of its solids). It is obvious that the disclosed prior art range of 8000mg (8gm) -12000 mg (12 gm) weight percent touches the claimed range lower value of 12,000 mg in 12, 000mg -20,000 mg weight percent of histidine content showing prima facie case of obviousness.

15. Regarding claim 4, Nakajima S et al teach about histidine enriched protein and source is from Bonito (Abstract, e.g. 'histidine is enriched in tuna and bonito').

Nakajima S et al do not teach about extraction from fish in powder form and processing to remove an odor and a flavor of said extract.

Ogura T et al. teach about activated charcoal treatment to decolorization and yielding a histidine product in crystal form to meet the standard for pharmaceutical ingredients (in Example 1, 2nd paragraph, e.g. 'The crystal purity of the crystals was 95% or more. The crystals were dissolved again and, upon decolorization with activated charcoal, recrystallized, yielding a product that met the standard for "L-histidine hydrochloride" in the Japanese standards for Pharmaceutical ingredients.). It is obvious that the crystal which is precipitated in pure form is known as L- Histidine hydrochloride monohydrate which is in the form of white crystalline powder as the product to be used. It is also obvious that the charcoal treatment not only decolorizes, but also deodorizes and gets rid of fishy flavor to meet the requirement of Histidine in pure form.

It would have been obvious to one of ordinary skill in the art to include the teaching of Ogura T et al. into Nakajima S et al. One of ordinary skill in the art would have been motivated to use active charcoal treated pure histidine which is free from odor and a flavor of said extract from where it was purified to have its use in any kind of food, both vegetarian and non vegetarian, as weight reduction diet composition, without fishy smell.

Conclusion

16. Any inquiry concerning the communication or earlier communications from the examiner should be directed to Bhaskar Mukhopadhyay whose telephone number is (571)-270-1139.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571)-272- 1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B.M. /
Patent Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794